REMARKS

The Office Action dated March 10, 2008 has been carefully considered. Claims 1, 3, 5, 27, 32, 34 and 35 have been amended. Claims 15-19 and 23 have been canceled. New claims 37 and 38 have been added. Claims 1-14, 20-22 and 24-38 are in this application.

Applicants thank the Examiner for the courtesies extended during a June 30, 2008 interview. Applicants confirm that the substance of the interview was the discussion of the disclosure of ¶ [0057] and the Sirhan et al. reference.

Claims 1, 3 and 5 have been amended to now recite that the stent is customized to the patient and pre-formed morphologically to match the profile and contour of the ascending aorta. Support for this amendment is found throughout the specification and in particular at ¶ [0009], [0010], [0014], [0037], [0054] and [0057]. Support for new claim 37 is found throughout the specification and in particular at ¶ [0057]. Support for new claim 38 is found throughout the specification and in particular at ¶ [0003], [0010], [0014], [0016], [0017] and [0034]. No new matter has been added.

Claim 33 is allowed.

The previously presented claims 1, 2, 4-10, 20-22, and 24-26 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,648,911 to Sirhan et al. Applicants submit that the teachings of this reference do not disclose or suggest the invention defined by the present claims.

Applicants submit that in the present invention, the stent is customized to the patient and pre-formed such that its size and shape conform morphologically to the ascending aorta, to which it will be applied. Accordingly, when the stent is applied it supports the exterior of the ascending aorta in substantially full contact therewith.

Sirhan et al. describe a method and device for treatment of a vulnerable tissue site, such as arterial and other aneurysms in the abdominal area or thoractic cavity.

In contrast to the invention defined by the present claims, Sirhan et al. do not teach or suggest a stent being customized to a patient and pre-formed having a size and shape which morphologically matches the morphological profile and contour of the ascending aorta. Further, Sirhan et al. do not teach or suggest that the stent supports the exterior of the ascending aorta in

substantially full contact therewith. In contrast, Sirhan et al. teach a containment member formed of a strand wound in a helical fashion. However, there is no teaching or suggestion of Sirhan et al. that the containment member is customized to a patient and pre-formed to morphologically match the morphological profile and contour of the ascending aorta. To the contrary, Sirhan et al teach a containment member having a tubular shape non-specific to a patient. Accordingly, Sirhan et al. do not teach all the features of the present claims and the invention defined by amended claim 1, 3 and 5 is not anticipated by Sirhan et al.

Dependent claims 2, 4, 6-10, 20-22 and 24-26 which are dependent on claim 1 are believed to be allowable for the same reasons that claim 1 is allowable.

Claims 3, 11, and 12 were rejected under 35 U.S.C. § 103 as obvious in view of Sirhan et al. in combination with U.S. Patent No. 6,197,050 to Eno et al.

Eno et al. describe a transmyocardial implant for establishing blood through a myocardium between a heart chamber and a lumen of a coronary vessel. The implant includes a hollow conduit having a first portion and a second portion. The first portion has an axial dimension aligned with an axis of the vessel. The second portion is sized to extend from the vessel through the myocardium into the heart chamber. A collar surrounds an exterior of the artery overlying the first portion and the first open end. The collar can have thickened and thinned portions.

In contrast to the invention defined by the present claims, Eno et al. do not teach or suggest a stent being customized to a patient and pre-formed having a size and shape which morphologically matches the morphological profile and contour of the blood vessel. In Eno et al., the stent is not customized and pre-formed to be in morphological relationship with the blood vessel. Rather, the stent of Eno et al. imposes its own morphology on the blood vessel. Accordingly, Eno et al. do not cure the deficiencies of Sirhan et al. described above and the invention defined by the present claims is not obvious in view of Sirhan et al. alone or in combination with Eno et al.

Claims 13 and 14 were rejected under 35 U.S.C. § 103 as obvious in view of Sirhan et al. in combination with U.S. Patent No. 6,554,856 to Doorly et al.

Doorly et al. disclose a stent for supporting part of a blood vessel. The stent includes a supporting portion around which or with which an associate graft can be placed.

In contrast to the invention defined by the present claims, Doorly et al. do not teach or suggest a stent having a size and shape which morphologically matches the morphological profile of the ascending aorta and that the stent supports the exterior of the ascending aorta in substantially full contact therewith. Rather, Doorly et al. is directed to a stent for supporting a blood vessel having a nonplanar curved form. There is no teaching or suggestion in Doorly et al. providing a stent having a size and shape which morphologically matches the morphological profile and contour of the ascending aorta. Rather, the stent of Doorly et al. imposes its own morphology on the blood vessel. Accordingly, Doorly et al. do not cure the deficiencies of Sirhan et al. described above and the invention defined by the present claims is not obvious in view of Sirhan et al. alone or in combination with Doorly et al.

Previously presented claims 27-31 and 36 were rejected under 35, U.S.C. § 103 as obvious in view of Sirhan et al. in combination with U.S. Patent No. 6,112,109 to D'Urso.

Claim 27 has been amended to be directed to a stent for morphologically fitting the ascending aorta. D'Urso does not teach or suggest the steps of producing a 3D computerised model from a scanned image of the ascending aorta to which the stent is in practice to be applied, and rapid prototyping the computerised 3D model in an appropriate material to provide the stent or a mould for the stent or a precursor thereof for morphologically matching the blood vessel by conforming morphologically to the contour of the ascending aorta of the patient and supporting the exterior of the ascending aorta in essentially full contact therewith. Instead, D'Urso teaches a method for stereolithographic construction of models including prostheses; see col. 4, lines 5-33. The prosthetic implant can replace an aortic junction. However, in D'Urso, there is no teaching or suggestion of providing a stent or model or precursor thereof for morphologically matching the contour of the ascending aorta and does not cure the deficiencies of Sirhan et al. described above.

Previously presented claim 34 was rejected under 35 U.S.C. § 103 as obvious in view of D'Urso in combination with U.S. Patent Application Publication No. 2006/0036311 to Nakayama et al.

Nakayama et al. teach a tubular stent matrix of which diameter is extendable and a flexible polymer layer covers the stent matrix. The polymer layer formed is perforated by excimer laser.

In contrast to the invention defined by the present claims, Nakayama et al. do not teach or suggest the method of manufacturing a stent by the steps of producing a 3D computerised model from a scanned image of the ascending aorta to which the stent is in practice to be applied, and rapid prototyping the computerised 3D model in an appropriate material to provide the stent or a mould for the stent or a precursor thereof for morphologically matching the ascending aorta and the stent is formed of polymeric material produced to conform morphologically to the 3D image in the form of a thin shell, the shell is mounted in a computer numerically controlled machine having multiple axes control. Accordingly, Nakayama et al. do not cure the deficiencies of D'Urso noted above and the invention defined by the present claims is not obvious in view of Nakayama et al.

Previously presented claims 32 and 35 were rejected under 35 U.S.C. § 103 as obvious in view of D'Urso in combination with U.S. Patent No. 6,899,728 to Phillips et al. D'Urso does not teach or suggest a method of manufacturing a stent for morphologically fitting a blood vessel of a patient to conform morphologically to the contour of the blood vessel by providing a sleeve to support its exterior in essentially full contact therewith.

Phillips et al. teach a reinforced graft formed on a flexible sheet of graft material which is sewn to a reinforcing wire. Sewing of the wire is carried out while the sheet is substantially planar by embroidery machines.

There is no teaching or suggestion in Phillips et al. of morphologically fitting a blood vessel of a patient to conform morphologically to the contour of the blood vessel by providing a sleeve to support its exterior in essentially full contact therewith. Further, Phillips et al. do not teach or suggest embroidery of a 3D image onto a 2D substrate element. Applicants submit it is only in hindsight that the Examiner can combine Phillips et al. directed to a reinforced graft with D'Urso directed to constructive modeling of articles. Further, even if the references could be combined, the teachings of the references do not disclose or suggest the invention defined by the present claims.

New claim 37 recites the feature of the sleeve of the present invention providing support and adjustment of the valve structure and the function of the stent is to prevent leakage of the valve. These features are not taught or suggested by the prior art of record.

New claim 38 provides a method for treating aortic root dissection in a patient which method is not taught or suggested in the prior art of record.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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Diane Dunn McKay, Esq.
Reg. No. 34,586
Attorney for Applicant

MATHEWS, SHEPHERD, McKAY & BRUNEAU, P.A.
29 Thanet Road, Suite 201
Princeton, NJ 08540
Tel: 609 924 8555
Fax: 609 924 3036